

Introduced by Senator Hill

February 10, 2016

An act ~~relating to outpatient health facilities~~; to amend the heading of Article 2.6 (commencing with Section 1645) of Chapter 4 of Division 2 of, and to amend the heading of Article 10 (commencing with Section 2190) of Chapter 5 of Division 2 of, and to add Sections 1645.5, 2197, 2454.6, and 2496.5 to, the Business and Professions Code, and to add Article 2.7 (commencing with Section 1223) of Chapter 1 of Division 2 to the Health and Safety Code, relating to antimicrobial stewardship.

LEGISLATIVE COUNSEL'S DIGEST

SB 994, as amended, Hill. ~~Outpatient health facilities; antimicrobial stewardship. Antimicrobial stewardship policies.~~

(1) Under existing law, the Dental Board of California, among other things, establishes requirements pursuant to which an applicant may obtain an initial 2-year license to practice dentistry and a 2-year renewal license, including that the board may require successful completion of continuing education as a condition to license renewal.

Under existing law, the Medical Practice Act, the Medical Board of California, the Osteopathic Medical Board of California, and the California Board of Podiatric Medicine establish requirements pursuant to which an applicant may obtain an initial 2-year license or subsequent 2-year renewal license to practice medicine as a podiatrist, as a physician and surgeon, osteopathic medicine as an osteopathic physician and surgeon, or podiatric medicine as a podiatrist, respectively. Under existing law, the Medical Board of California is required to adopt and administer standards for the continuing education of physicians and

surgeons and each year audits a random sample of physicians and surgeons who have reported compliance with those requirements and requires a noncompliant licensee to make up the deficiency during the next renewal period. Under existing law, a licensee who fails to so comply is ineligible for a subsequent renewal license until he or she documents compliance to the board. Existing law provides for similar continuing education requirements as a condition of obtaining a renewal license to practice osteopathic medicine and podiatric medicine.

This bill would require a “covered licensee,” defined as a dentist, physician and surgeon, osteopathic physician and surgeon, or person licensed to practice podiatric medicine, who practices in a setting other than a clinic, general acute care hospital, or skilled nursing facility, to adopt and implement an antimicrobial stewardship policy consistent with specified guidelines or methods of intervention, as defined, before applying for a renewal license and, upon applying for a renewal license, to certify in writing, on a form prescribed by the respective licensing board, that he or she has both adopted an antimicrobial stewardship policy and is in compliance with that policy. The bill would require those licensing boards to audit, during each year, a random sample of covered licensees who have certified compliance with these requirements and would limit the audit of an individual covered licensee to once every 4 years. The bill would require a covered licensee who is selected for audit to submit to the board, on a form prescribed by the board, a copy of his or her antimicrobial stewardship policy. The bill would require the respective licensing board, that determines that its audited covered licensee has failed to comply with these requirements, to require that covered licensee to comply with these requirements during the following renewal period. The bill would provide that a covered licensee who fails to comply is ineligible for license renewal until he or she has documented compliance.

Under

(2) *Under existing law, health facilities, including, among others, general acute care hospitals, skilled nursing facilities, primary care clinics, and specialty clinics, are licensed and regulated by the State Department of Public Health, and a violation of those provisions is a crime. Existing law requires that each general acute care hospital, on or before July 1, 2015, adopt and implement an antimicrobial stewardship policy in accordance with guidelines established by the federal government and professional organizations that includes a process to evaluate the judicious use of antibiotics, as specified. Existing*

law requires each skilled nursing facility, on or before January 1, 2017, to adopt and implement an antimicrobial stewardship policy consistent with guidelines developed by the federal Centers for Disease Control and Prevention and other specified entities.

~~This bill would state the intent of the Legislature to enact legislation that would promote the establishment of antimicrobial stewardship programs or policies in outpatient health facilities. The bill makes related findings and declarations.~~ *would, beginning January 1, 2018, require a clinic to adopt and implement an antimicrobial stewardship policy consistent with specified guidelines or methods of intervention, as defined. Because this bill would create new crimes, the bill would impose a state-mandated local program.*

(3) The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: ~~no~~-yes.
State-mandated local program: ~~no~~-yes.

The people of the State of California do enact as follows:

- 1 ~~SECTION 1.~~ It is the intent of the Legislature to enact
- 2 ~~legislation that would promote the establishment of antimicrobial~~
- 3 ~~stewardship programs or policies in outpatient health facilities.~~
- 4 ~~SEC. 2.~~
- 5 SECTION 1. The Legislature finds and declares all of the
- 6 following:
- 7 (a) The overuse and misuse of antibiotics can lead to the
- 8 development of antibiotic-resistant infections, a major public health
- 9 threat.
- 10 (b) The federal Centers for Disease Control and Prevention
- 11 (CDC) estimates that at least 2,000,000 Americans are infected
- 12 with, and at least 23,000 Americans die as a result of,
- 13 antibiotic-resistant infections every year, resulting in at least \$20
- 14 billion in direct health care costs and at least \$35 billion in lost
- 15 productivity in the United States.
- 16 (c) Antibiotic resistance is a growing threat. A recent study
- 17 commissioned by the United Kingdom determined that by 2050,

1 worldwide, more people will die from antibiotic-resistant infections
2 than from cancer.

3 (d) The overuse and misuse of antibiotics in human medicine
4 is a significant factor driving the development of antibiotic
5 resistance, and a majority of antibiotics are prescribed in outpatient
6 settings, including primary care physician offices, outpatient
7 settings where physician assistants and nurse practitioners work,
8 dentist offices, and other specialty health care providers.

9 (e) According to the CDC, in one year, 262.5 million courses
10 of antibiotics are written in outpatient settings. This equates to
11 more than five prescriptions written each year for every six people
12 in the United States. The CDC estimates that over one-half of the
13 antibiotics prescribed in outpatient settings are unnecessary.

14 (f) More than 10 million courses of antibiotics are prescribed
15 each year for viral conditions that do not benefit from antibiotics.

16 (g) Antibiotic stewardship programs, which are already required
17 in general acute care hospitals and skilled nursing facilities in the
18 state, but not in outpatient settings, are an effective way to reduce
19 inappropriate antibiotic use and the prevalence of
20 antibiotic-resistant infections.

21 (h) The President's National Action Plan for Combating
22 Antibiotic-Resistant Bacteria calls for the establishment of
23 antibiotic stewardship activities in all health care delivery settings,
24 including outpatient settings, by 2020.

25 *SEC. 2. The heading of Article 2.6 (commencing with Section*
26 *1645) of Chapter 4 of Division 2 of the Business and Professions*
27 *Code is amended to read:*

28
29 *Article 2.6. Continuing Education and Antimicrobial*
30 *Stewardship*
31

32 *SEC. 3. Section 1645.5 is added to the Business and Professions*
33 *Code, to read:*

34 *1645.5. (a) For purposes of this section the following*
35 *definitions apply:*

36 *(1) "Antimicrobial stewardship policy" means efforts to promote*
37 *the appropriate and optimal selection, dosage, and duration of*
38 *antimicrobials for patients, with the goal of reducing antimicrobial*
39 *overuse and misuse and minimizing the development of*

1 *antimicrobial resistant infections, that is consistent with one of*
2 *the following parameters:*

3 (A) *Antimicrobial stewardship guidelines published by the*
4 *federal Centers for Disease Control and Prevention, the federal*
5 *Centers for Medicare and Medicaid Services, the Society for*
6 *Healthcare Epidemiology of America, the Infectious Diseases*
7 *Society of America, or similar recognized professional*
8 *organizations.*

9 (B) *Evidence-based methods. To the extent practicable,*
10 *antimicrobial stewardship policies based on proven,*
11 *evidence-based methods should include more than one intervention*
12 *or component.*

13 (2) A “covered licensee” means *a dentist who practices dentistry*
14 *in a setting other than a clinic licensed pursuant to Section 1204*
15 *of the Health and Safety Code, a general acute care hospital as*
16 *defined in subdivision (a) of Section 1250 of the Health and Safety*
17 *Code, or a skilled nursing facility as defined in subdivision (c) of*
18 *Section 1250 of the Health and Safety Code.*

19 (3) “Evidence-based methods” means *antimicrobial prescribing*
20 *intervention methods that have been proven effective through*
21 *outcome evaluations or studies, including, but not limited to, audit*
22 *and feedback, academic detailing, clinical decision support,*
23 *delayed prescribing practices, poster-based interventions,*
24 *accountable justification, and peer comparison.*

25 (b) A covered licensee shall adopt and implement an
26 antimicrobial stewardship policy before applying for a renewal
27 license.

28 (c) Upon filing an application with the board for a renewal
29 license, a covered licensee shall certify in writing, on a form
30 prescribed by the board, that he or she has both adopted an
31 antimicrobial stewardship policy pursuant to subdivision (b) and
32 is in compliance with that policy.

33 (d) (1) The board shall audit during each year a random sample
34 of covered licensees who have certified compliance pursuant to
35 subdivision (c). The board shall not audit an individual covered
36 licensee more than once every four years.

37 (2) A covered licensee who is selected for audit shall submit to
38 the board, on a form prescribed by the board, a copy of his or her
39 antimicrobial stewardship policy.

1 (e) If the board determines that an audited covered licensee has
2 failed to comply with subdivision (b), the board shall require that
3 covered licensee to comply with subdivision (b) during the
4 following renewal period. If the covered licensee fails to comply
5 within that period, he or she is ineligible for a subsequent license
6 renewal until he or she has documented compliance.

7 SEC. 4. The heading of Article 10 (commencing with Section
8 2190) of Chapter 5 of Division 2 of the Business and Professions
9 Code is amended to read:

10
11 Article 10. Continuing Medical Education and Antimicrobial
12 Stewardship
13

14 SEC. 5. Section 2197 is added to the Business and Professions
15 Code, to read:

16 2197. (a) For purposes of this section the following definitions
17 apply:

18 (1) “Antimicrobial stewardship policy” means efforts to promote
19 the appropriate and optimal selection, dosage, and duration of
20 antimicrobials for patients, with the goal of reducing antimicrobial
21 overuse and misuse and minimizing the development of
22 antimicrobial resistant infections, that is consistent with one of
23 the following parameters:

24 (A) Antimicrobial stewardship guidelines published by the
25 federal Centers for Disease Control and Prevention, the federal
26 Centers for Medicare and Medicaid Services, the Society for
27 Healthcare Epidemiology of America, the Infectious Diseases
28 Society of America, or similar recognized professional
29 organizations.

30 (B) Evidence-based methods. To the extent practicable,
31 antimicrobial stewardship policies based on proven,
32 evidence-based methods should include more than one intervention
33 or component.

34 (2) A “covered licensee” means a physician and surgeon who
35 practices medicine in a setting other than a clinic licensed pursuant
36 to Section 1204 of the Health and Safety Code, a general acute
37 care hospital as defined in subdivision (a) of Section 1250 of the
38 Health and Safety Code, or a skilled nursing facility as defined in
39 subdivision (c) of Section 1250 of the Health and Safety Code.

1 (3) “Evidence-based methods” means antimicrobial prescribing
2 intervention methods that have been proven effective through
3 outcome evaluations or studies, including, but not limited to, audit
4 and feedback, academic detailing, clinical decision support,
5 delayed prescribing practices, poster-based interventions,
6 accountable justification, and peer comparison.

7 (b) A covered licensee shall adopt and implement an
8 antimicrobial stewardship policy before applying for a renewal
9 license.

10 (c) Upon filing an application with the board for a renewal
11 license, a covered licensee shall certify in writing, on a form
12 prescribed by the board, that he or she has both adopted an
13 antimicrobial stewardship policy pursuant to subdivision (b) and
14 is in compliance with that policy.

15 (d) (1) The board shall audit during each year a random sample
16 of covered licensees who have certified compliance pursuant to
17 subdivision (c). The board shall not audit an individual covered
18 licensee more than once every four years.

19 (2) A covered licensee who is selected for audit shall submit to
20 the board, on a form prescribed by the board, a copy of his or her
21 antimicrobial stewardship policy.

22 (e) If the board determines that an audited covered licensee has
23 failed to comply with subdivision (b), the board shall require that
24 covered licensee to comply with subdivision (b) during the
25 following renewal period. If the covered licensee fails to comply
26 within that period, he or she is ineligible for a subsequent license
27 renewal until he or she has documented compliance.

28 SEC. 6. Section 2454.6 is added to the Business and Professions
29 Code, to read:

30 2454.6. (a) For purposes of this section the following
31 definitions apply:

32 (1) “Antimicrobial stewardship policy” means efforts to promote
33 the appropriate and optimal selection, dosage, and duration of
34 antimicrobials for patients, with the goal of reducing antimicrobial
35 overuse and misuse and minimizing the development of
36 antimicrobial resistant infections, that is consistent with one of
37 the following parameters:

38 (A) Antimicrobial stewardship guidelines published by the
39 federal Centers for Disease Control and Prevention, the federal
40 Centers for Medicare and Medicaid Services, the Society for

1 *Healthcare Epidemiology of America, the Infectious Diseases*
2 *Society of America, or similar recognized professional*
3 *organizations.*

4 *(B) Evidence-based methods. To the extent practicable,*
5 *antimicrobial stewardship policies based on proven, evidence*
6 *based methods should include more than one intervention or*
7 *component.*

8 *(2) A “covered licensee” means an osteopathic physician and*
9 *surgeon who practices osteopathic medicine in a setting other than*
10 *a clinic licenced pursuant to Section 1204 of the Health and Safety*
11 *Code, a general acute care hospital as defined in subdivision (a)*
12 *of Section 1250 of the Health and Safety Code, or a skilled nursing*
13 *facility as defined in subdivision (c) of Section 1250 of the Health*
14 *and Safety Code.*

15 *(3) “Evidence-based methods” has the same meaning as in*
16 *paragraph (3) of subdivision (a) of Section 2197.*

17 *(b) A covered licensee shall adopt and implement an*
18 *antimicrobial stewardship policy before applying for a renewal*
19 *license.*

20 *(c) Upon filing an application with the board for a renewal*
21 *license, a covered licensee shall certify in writing, on a form*
22 *prescribed by the board, that he or she has both adopted an*
23 *antimicrobial stewardship policy pursuant to subdivision (b) and*
24 *is in compliance with that policy.*

25 *(d) (1) The board shall audit during each year a random sample*
26 *of covered licensees who have certified compliance pursuant to*
27 *subdivision (c). The board shall not audit an individual covered*
28 *licensee more than once every four years.*

29 *(2) A covered licensee who is selected for audit shall submit to*
30 *the board, on a form prescribed by the board, a copy of his or her*
31 *antimicrobial stewardship policy.*

32 *(e) If the board determines that an audited covered licensee has*
33 *failed to comply with subdivision (b), the board shall require that*
34 *licensee to comply with subdivision (b) during the following*
35 *renewal period. If the covered licensee fails to comply within that*
36 *period, he or she is ineligible for a subsequent license renewal*
37 *until he or she has documented compliance.*

38 *SEC. 7. Section 2496.5 is added to the Business and Professions*
39 *Code, to read:*

1 2496.5. (a) For purposes of this section the following
2 definitions apply:

3 (1) “Antimicrobial stewardship policy” means efforts to promote
4 the appropriate and optimal selection, dosage, and duration of
5 antimicrobials for patients, with the goal of reducing antimicrobial
6 overuse and misuse and minimizing the development of
7 antimicrobial resistant infections, that is consistent with one of
8 the following parameters:

9 (A) Antimicrobial stewardship guidelines published by the
10 federal Centers for Disease Control and Prevention, the federal
11 Centers for Medicare and Medicaid Services, the Society for
12 Healthcare Epidemiology of America, the Infectious Diseases
13 Society of America, or similar recognized professional
14 organizations.

15 (B) Evidence-based methods. To the extent practicable,
16 antimicrobial stewardship policies based on proven, evidence
17 based methods should include more than one intervention or
18 component.

19 (2) A “covered licensee” means a podiatrist who practices
20 podiatric medicine in a setting other than a clinic licensed pursuant
21 to Section 1204 of the Health and Safety Code, a general acute
22 care hospital as defined in subdivision (a) of Section 1250 of the
23 Health and Safety Code, or a skilled nursing facility as defined in
24 subdivision (c) of Section 1250 of the Health and Safety Code.

25 (3) “Evidence-based methods” has the same meaning as in
26 paragraph (3) of subdivision (a) of Section 2197.

27 (b) A covered licensee shall adopt and implement an
28 antimicrobial stewardship policy before applying for a renewal
29 license.

30 (c) Upon filing an application with the board for a renewal
31 license, a covered licensee shall certify in writing, on a form
32 prescribed by the board, that he or she has both adopted an
33 antimicrobial stewardship policy pursuant to subdivision (b) and
34 is in compliance with that policy.

35 (d) (1) The board shall audit during each year a random sample
36 of covered licensees who have certified compliance pursuant to
37 subdivision (c). The board shall not audit an individual covered
38 licensee more than once every four years.

1 (2) A covered licensee who is selected for audit shall submit to
2 the board, on a form prescribed by the board, a copy of his or her
3 antimicrobial stewardship policy.

4 (e) If the board determines that an audited covered licensee has
5 failed to comply with subdivision (b), the board shall require that
6 licensee to comply with subdivision (b) during the following
7 renewal period. If the covered licensee fails to comply within that
8 period, he or she is ineligible for a subsequent license renewal
9 until he or she has documented compliance.

10 SEC. 8. Article 2.7 (commencing with Section 1223) is added
11 to Chapter 1 of Division 2 of the Health and Safety Code, to read:

12
13 Article 2.7. Antimicrobial Stewardship Guidelines

14
15 1223. (a) For purposes of this article the following definitions
16 apply.

17 (1) “Antimicrobial stewardship policy” means efforts to promote
18 the appropriate and optimal selection, dosage, and duration of
19 antimicrobials for patients, with the goal of reducing antimicrobial
20 overuse and misuse and minimizing the development of
21 antimicrobial resistant infections.

22 (2) “Evidence-based methods” means antimicrobial prescribing
23 intervention methods that have been proven effective through
24 outcome evaluations or studies, including, but not limited to, audit
25 and feedback, academic detailing, clinical decision support,
26 delayed prescribing practices, poster-based interventions,
27 accountable justification, and peer comparison.

28 (b) On or before January 1, 2018, a primary care clinic or
29 specialty clinic shall adopt and implement an antimicrobial
30 stewardship policy that is consistent with one of the following
31 parameters:

32 (1) Antimicrobial stewardship guidelines published by the
33 federal Centers for Disease Control and Prevention, the federal
34 Centers for Medicare and Medicaid Services, the Society for
35 Healthcare Epidemiology of America, the Infectious Diseases
36 Society of America, or similar recognized professional
37 organizations.

38 (2) Evidence-based methods. To the extent practicable,
39 antimicrobial stewardship policies based on proven,

1 *evidence-based methods should include more than one intervention*
2 *or component.*

3 *SEC. 9. No reimbursement is required by this act pursuant to*
4 *Section 6 of Article XIII B of the California Constitution because*
5 *the only costs that may be incurred by a local agency or school*
6 *district will be incurred because this act creates a new crime or*
7 *infraction, eliminates a crime or infraction, or changes the penalty*
8 *for a crime or infraction, within the meaning of Section 17556 of*
9 *the Government Code, or changes the definition of a crime within*
10 *the meaning of Section 6 of Article XIII B of the California*
11 *Constitution.*